

CLAIM AMENDMENT

Please amend the claims as set forth below:

1. (Currently amended) A soybean seed comprising genes conferring resistance to at least the herbicides glyphosate and glufosinate.
2. (Currently amended) A soybean plant produced by growing the seed of claim 1.
3. (Canceled)
4. (Original) Pollen of the plant of claim 2.
5. (Original) Ovule or ovules of the plant of claim 2.
6. (Original) Tissue culture of the plant of claim 2.
7. (Original) A plant regenerated from the tissue culture of claim 6.
8. (Original) A method to produce a hybrid seed comprising crossing a first parent plant with a second parent plant and harvesting the resultant F1 hybrid seed, wherein said first or second parent plant is the plant of claim 2.
9. (Previously presented) A first generation (F1) hybrid plant produced by growing said hybrid seed of claim 8, wherein the hybrid plant comprises said genes.
10. (Previously presented) A progeny plant of the plant of claim 9, wherein the progeny plant comprises said genes.
- 11-12. (Canceled)
13. (Previously presented) The soybean plant of claim 2, wherein said plant has a commercially acceptable grain yield.
- 14-24. (Canceled)
25. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises a gene conferring resistance to isoxoflutole.
- 26-32. (Canceled)
33. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises a gene conferring resistance to atrazine.

- 34. (Canceled)
- 35. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises a gene conferring resistance to ALS inhibitor herbicides.
- 36-38. (Canceled)
- 39. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises genes conferring resistance to atrazine and ALS inhibitor herbicides.
- 40-41. (Canceled)
- 42. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises genes conferring resistance to ALS inhibitor and isoxoflutole herbicides.
- 43. (Withdrawn by examiner) The soybean seed of claim 1, wherein said seed further comprises genes conferring resistance to atrazine, ALS inhibitor and isoxoflutole herbicides.
- 44-49. (Canceled)

RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1, 2, 4-10, 13, 25, 33, 35, 39, 42 and 43 are pending in the case. Claims 25, 33, 35, 39, 42 and 43 have been withdrawn by the Examiner as drawn to non-elected subject matter. The presence of generic linking claim 11 has been acknowledged in the Action. However, this claim has been canceled. Applicants note that, in the present claims, claim 1 is generic and links the remaining claims. Applicants respectfully request that the presence of this linking claim be acknowledged on the record.

B. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claim 13 for lack of antecedent basis for “the soybean plant.” In response, it is noted that claims 1 and 2 have been amended herein to recite a soybean seed and plant. It is believed that the rejection is now moot in light of the amendment.

In view of the foregoing, removal of the rejection is respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §102(b)/103(a)

The Action has rejected claims 1, 2, 4-10 and 13 under 35 U.S.C. §103 as being obvious in two separate rejections. Applicants’ response to each rejection is set forth below.

(1) The Action rejects claims 1, 2, 4-10 and 13 under 35 U.S.C. §103 as being obvious over Shankle *et al.* (*Abst. Meet. Weed Sci. Soc. Am.*; 37,88 (1997)) in view of Padgette (*Crop Sci.*, 35:1451-1461 (1995)). The first line of the rejection states that the cited references are Shankle *et al.* and Barry *et al.*, but Barry *et al.* is not discussed in the rejection whereas Padgette *et al.* is. It is therefore believed that the reference to Barry *et al.* was inadvertent.

With regard to the Shankle *et al.* reference, Applicants note that this is dated to 1997 in the Action. However, the publication date is not given in the Action or on the reference. The current application has an effective filing date of March 7, 1997, based on the filing date of parent application U.S.S.N. 08/813,788, now issued as U.S. Patent No. 6,376,754. It therefore has not been shown that Shankle *et al.* is prior art to the current application. In the event that the rejection is maintained, Applicants therefore respectfully request that it be shown that the date of publication of the reference is prior to March 7, 1997.

Applicants respectfully traverse the rejection. As explained in the attached Declaration of Dr. Joseph R. Byrum Under 37 C.F.R. §1.132 (Appendix 1), and below, one of skill in the art would have been without any reasonable expectation of success in arriving at the invention based on the cited references and teaching in the art generally. At best, it would have been “obvious to try” to make the claimed invention, which the Federal Circuit has specifically held is insufficient to support a rejection under §103.

As explained in the Declaration of Dr. Byrum, a soybean variety had never been developed having more than one herbicide resistance transgene combined into a single soybean plant prior to the current invention. An assertion that any two given herbicide resistance transgenes previously expressed individually can be expressed in a single variety must therefore be taken as speculation. Dr. Byrum explains that the expression of herbicide resistance transgenes requires manipulation of complex metabolic pathways of plant cells. Herbicides such as glyphosate and glufosinate normally interfere with these pathways. For example, glyphosate inhibits the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) and glufosinate the phosphinothricin acetyl transferase (PAT) enzyme. These enzymes are both involved in the synthesis of amino acids in plant cells and the lack of function of the enzymes kills the plant.

Engineering resistance to the herbicides requires modifying and/or overexpression of altered forms of the enzymes with decreased herbicide susceptibility.

Dr. Byrum explains that soybean plants do not naturally exhibit herbicide tolerance, and therefore the results of a given modification are unpredictable. **Appendix 1**, p. 3. Transgene expression causes complex pleiotropic effects that can vary depending upon factors such as the location of insertion of the transgene in a genome, the transgene being expressed, the genotype of the host soybean plant, and the regulatory elements and any enhancers used to express the transgene. The expression of enzymes not normally present in a plant also creates a “metabolic drag” reducing energy from the diversion of resources to the expression of the transgene. Herbicide resistance traits add the uncertainty of potential interactions among interrelated metabolic pathways, including negative or positive feedback regulation of different pathways from altered substrate or precursor production.

It is further indicated by Dr. Byrum that the difficulties of engineering herbicide resistance are exponential when two herbicide resistance transgenes are combined. For example, herbicide mixtures can have a synergistic effect and therefore tolerance to glyphosate and glufosinate individually would not necessarily be indicative of tolerance to a combination of these herbicides. Second, metabolic drag and/or pleiotropic effects could have limited the availability of substrates in the metabolic pathways necessary for the co-expression of glyphosate and glufosinate tolerance transgenes. Third, certain traits are known to be negatively correlated, and therefore a negative correlation could also have been observed for the combination of glyphosate and glufosinate tolerance traits, absent evidence to the contrary.

Based on the foregoing, Dr. Byrum has concluded that the absence of pleiotropic or other effects preventing the combination of these traits would have been speculation prior to the studies in the application. Dr. Byrum therefore states that one of skill in the art prior to the invention would have been without any reasonable expectation that transgenes could be co-expressed in a single soybean plant to achieve resistance to glyphosate and glufosinate.

Appendix 1, p.4.

The evidence presented above demonstrates that a reasonable expectation of success was missing in the art. Such an expectation of success must be present and established on the record in order to maintain an obviousness rejection. *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991), *see also*, M.P.E.P. § 2142. The rejection must further be supported by “substantial evidence” in accordance with the Administrative Procedure Act (“APA”). *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000); 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). Here, Applicants have affirmatively established that such a reasonable expectation was absent and therefore the rejection cannot stand. Removal of the rejection under 35 U.S.C. § 103 is thus respectfully requested.

(2) The Action rejects claims 1, 2, and 4-10 under 35 U.S.C. §103 as being obvious over Dyer in view of Padgett *et al.* The Action states in particular that the references show tobacco plants that, individually, possess genes conferring resistance to glyphosate or glufosinate and that it would be obvious to combine these.

In response, it is noted that the rejection is directed only to claims that are not directed to soybean plants. The failure by Applicants to direct these claims to soybean plants was inadvertent, as illustrated by the dependency of the withdrawn claims. Claims 1 and 2 have been

corrected herein to specify soybean plants. It is believed that the rejection is now moot in light of the amendment, as neither reference is asserted to disclose transgenic soybean seeds or plants.

In view of the foregoing, removal of the rejection is respectfully requested.

D. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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